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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,622	12/12/2001	Paul F. Laeseke	960296.98636	5043

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QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE, SUITE 2040
MILWAUKEE, WI 53202-4497

EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/021,622

Applicant(s)

LAESEKE ET AL.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 24 April 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed April 24, 2003. The Examiner acknowledges the amendments to the specification; the proposed corrections to the drawings; and the amendments to claims 1, 6, 7, 14-16, 18 and 20. Claims 1-20 are pending.

Drawings

2. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on April 24, 2003 have been approved by the Examiner. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: In view of Applicant's arguments regarding the rejection of claim 9 under 25 USC 112, first paragraph, the rejection has been withdrawn. Applicant contends that claim 9, as part of the specification, would enable one skilled in the art to understand the limitations proposed. Since the limitations of claim 9 are part of the original disclosure, an amendment to the specification to reflect the limitations thereof would not constitute new matter. Therefore, an amendment to the specification to provide antecedent basis for the limitations of claim 9 is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-5, 7-10 and 16-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Wood ('007). Wood teaches a biopsy apparatus with radio frequency cauterization and methods for its use. The apparatus is a biopsy needle assembly including an introducer shaft **18** that is a hollow, electrically conductive tube. The introducer shaft is covered by an outer insulating covering **20** such that an exposed first end of the shaft forms an electrically conductive surface **32** that extends continuously between 1mm and 5cm, preferably 2cm, as measured along the insertion path. A biopsy needle **38** including a sampling means **52** is fit in the introducer shaft to be guided thereby. The biopsy needle **38** can be a conductive stylet that may be supported by the introducer shaft with an insulating covering disposed between the stylet and the shaft. The cauterization electrode **32** may be a monopolar electrode and require use of large ground electrode pads (paragraph [0053]) that complete the circuit through a RF electrical source. A temperature sensor may be positioned at the electrically conductive surface to assist in monitoring and controlling the cauterizing function (paragraph [0039]). In operation, the introducer shaft is inserted percutaneously into a patient along an insertion path to locate the

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conductive surface at or in proximity to a biopsy site; the biopsy needle is guided with the introducer shaft to the biopsy shaft to obtain a tissue sample; the biopsy sample is removed from the patient; and a cauterizing electrical power source is connected to the electrically conductive surface as the introducer shaft is withdrawn to cauterize tissue along the insertion path. The temperature at the electrically conductive surface can be measured and the withdrawal of the introducer shaft may be adjusted according to the measurements.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wood ('007) in view of Ouchi ('221). Wood teaches all of the limitations of the claims, including the use of a stylet having a blunt tip, except that the stylet has a rounded tip. Ouchi teaches an electrocautery stylet **12** that has a hemispherical tip (figure 7). It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a stylet having a rounded tip with an introducer shaft similar to that of Wood in light of the teachings of Ouchi in order to prevent unnecessary damage to the tissue and bleeding.

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8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wood ('007) in view of Moorman et al. ('033). Wood teaches all of the limitations of the claims except that indicia are provided on the introducer shaft to indicate the position of the conductive surface of the introducer shaft. Moorman et al. teach a track ablation device including an introducer shaft **10** having indicia **85,86** disposed on its outer surface which allow a clinician to gauge the position of the shaft and a conductive surface of the shaft within the body. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide indicia on an introducer shaft similar to that of Wood in light of the teachings of Moorman et al. in order to indicate the location of the conductive end surface of the introducer shaft while the shaft is disposed within the body.

9. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wood ('007) in view of Shikhman et al. ('636). Wood teaches all of the limitations of the claims except that the assembly includes an audio or visual indicator that guides the user based on at least one of temperature, electrical resistance or electrical power at the conductive surface. Shikhman et al. teach conductive body tissue penetrating device that includes an audio or visual indicator for guiding a user of the device based on the electrical power at the electrically conductive surface. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide an indicator in combination with an introducer shaft similar to that of Wood in light of the teachings of Shikhman et al. in order to guide a user in manipulating the device based on the electrical power at the electrically conductive surface.

10. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wood ('007) in view of Kieturakis ('626). Wood teaches all of the limitations of the claims except that a retracting mechanism is provided to automatically retract the introducer shaft. Kieturakis teaches that it is known in the art to use a controller **150** to automatically withdraw a biopsy assembly from a patient where the assembly is withdrawn based upon various parameters. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide a controller to automatically retract an introducer shaft similar to that of Wood in light of the teachings of Kieturakis in order to withdraw the introducer shaft with greater control than can be provided by manual operation.

Response to Arguments

11. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that Eggers et al. fail to teach or suggest a needle assembly including a skin electrode and teach away from monopolar operation of the introducer shaft, as claimed in claim 1. Applicant further contends that Eggers et al. fail to teach or suggest that the introducer shaft is withdrawn to cauterize tissue along the insertion path or that cauterizing power is disconnected prior to withdrawing the conductive surface through the skin, as claimed by Applicant in claims 16 and 18. These arguments are moot in view of the new grounds of rejection citing Wood set forth hereinabove.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Garcia ('079) teach a cauterizing biopsy needle sheath. Levin ('030) teaches a biopsy needle with cauterization features.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9323 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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July 10, 2003